UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

vs.

VYSIS, INC.,

Defendant.

CASE NO. 99-CV-2668 H (AJB)

ORDER DENYING (1) VYSIS INC.'S REQUEST FOR RECONSIDERATION OF THE COURT'S JUNE 20, 2001 ORDER, AND (2) GEN-PROBE INCORPORATED'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NONINFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS

On October 16, 2001, Gen-Probe Incorporated ("Gen-Probe") filed a motion for partial summary judgment of noninfringement under the doctrine of equivalents. The Court originally scheduled the hearing date for that motion for November 13, 2001.

On October 30, 2001, Vysis, Inc. ("Vysis") filed its opposition papers to Gen-Probe's motion and included a request for reconsideration in those papers. Moreover, in its opposition, Vysis moved for a continuance under Fed. R. Civ. P. 56(f) to depose the expert who filed a declaration in support of Gen-Probe's motion. The next day, on October 31, 2001, Vysis filed an ex parte motion for continuance based on the unavailability of its lead counsel on the original hearing date. Gen-Probe filed its opposition to the Rule 56(f) and ex parte motions on November 1, 2001.

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After considering the requests for continuance along with the opposition to those motions, the Court granted a one-week continuance of the hearing date under Rule 56(f) to permit Vysis to depose Gen-Probe's expert. Since it granted a continuance under Rule 56(f), the Court dismissed the ex parte motion as moot. The Court further issued a briefing and scheduling order permitting Vysis to file a supplemental opposition on November 9, 2001 and Gen-Probe to file its reply on November 13, 2001. The hearing on the motion for partial summary judgment was continued to November 19, 2001. On November 9, 2001, Vysis timely filed its supplemental opposition. On November 13, 2001, Gen-Probe filed its reply.

On November 19, 2001, the Court held a hearing on the pending motions. At that hearing, R. William Bowen and Stephen Swinton appeared on behalf of Gen-Probe. Charles Lipsey and John L'Estrange appeared on behalf of Vysis, while Thomas Banks and Norval Galloway appeared telephonically on behalf of Vysis.

The Court has reviewed the papers submitted in relation to these motions, heard the parties' argument, and considered the controlling law. For the reasons provided below, the Court denies (1) Vysis' request for reconsideration of the Court's June 20, 2001 Order as submitted in Vysis' opposition and supplemental opposition papers, and (2) Gen-Probe's motion for partial summary judgment of noninfringement under the doctrine of equivalents.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Complaint

On March 13, 2001, plaintiff Gen-Probe, Inc. filed a Second Amended Complaint for declaratory relief and unfair competition related to a patent and license agreement with the defendant Vysis, Incorporated. This case is styled as a declaratory judgment action brought by Gen-Probe. Thus, Vysis, the owner of U.S. Patent No. 5,750,338 ("the '338 patent"), is the defendant.

Gen-Probe asks the Court to declare the '338 patent invalid and to further find that Gen-Probe's current and anticipated activities do not infringe any valid claims of the '338 patent. In its Second Amended Complaint, Gen-Probe asserts the following causes of action: (1) non-infringement of the '338 patent; (2) invalidity of the '338 patent; (3) declaratory relief; (4) unfair competition; (5) unenforceability of the '338 patent.

B. The '338 Patent

The '338 patent relates generally to methods for use in nucleic acid diagnostics, including the use of nucleic acid "probes" to detect infectious organisms. The '338 patent describes methods by which nucleic acids may be "captured" onto solid supports and "amplified," so that small quantities of nucleic acids may be then detected by the probes.

A discussion of certain scientific facts is necessary to facilitate an understanding of the patent. Each cell in an organism contains information-encoding elements, called genes, that direct the functioning of the cell, the production of specific proteins, and the development of the organism. ('338 patent, col. 2, ln. 35-37). Genes are comprised of molecules of deoxyribonucleic acid ("DNA"). (Id, col. 2, ln. 20-21).

DNA consists of two long chains that wrap around each other in the shape of a double-stranded spiral helix. (Id., col. 2, ln. 21-22). The twisted DNA strands are held together by hydrogen bonds between molecules called nucleotides. (Id., col. 2, ln. 24-27 and 33-35). There are only four different nucleotides in a DNA chain, each containing one of the bases adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T"). (Id., col. 2, ln. 22-24). Because of the nucleotides' chemical structure, A will only pair with T, and C will only pair with G. (Id., col. 2, ln. 27-30). Given this strict complementary pairing, the order of the nucleotides on one side of a DNA strand determines the order on the other side of the strand. (Id., col. 2, ln. 33-35). In a gene, the order of these four nucleotides constitute the cell's genetic code and encodes for the sequence of a particular protein.

DNA directs cells to make proteins through a two-step process of transcription and translation. Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1323 (Fed. Cir. 2001) (providing a detailed discussion of the biological process of transcription and translation). First, transcription occurs. Id. During transcription, information is transferred from the DNA sequence of nucleotides by copying a specific DNA region into a chemically and functionally different type of molecule called ribonucleic acid ("RNA"). Id. RNA is a long single strand of linked nucleotides similar to DNA, with one major difference: RNA contains the base uracil ("U") in place of thymine. Id. In transcription, specific nucleotide sequences on the DNA determine where the RNA copy begins and ends. Id. The second

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step in protein synthesis is translation. Id. During translation, the cell mechanisms translate the RNA nucleotide sequence into the amino acid sequence of the corresponding protein. Id.

The '338 patent relies on these basic scientific facts in its teachings of methods to "target capture" and "amplify" target DNA and RNA molecules. "Target capture" techniques are used in nucleic acid methods to isolate a particular nucleic acid of interest prior to detection or other steps. ('338 patent, col. 1, ln. 23-29). In target capture methods, the target nucleic acid is bound to a solid support, such as a filter, particle, or bead, that allows the target to be removed from the sample in which it was originally contained. (Id., col. 4, ln. 18-24).

After target capture, it is sometimes necessary to achieve a detectable level of target organisms in a sample by increasing the target organism's nucleic acid through a "nucleic acid amplification" process. (Id., col. 9, ln. 42-53). This "amplification" process uses polymerase enzymes and primers. (E.g., id., col. 31, ln. 25-54).

This amplification process operates analogously to the way DNA makes copies of itself through a "replication"process. (Declaration of Dr. Joseph O. Falkinham in Support of Gen-Probe's Motion for Partial Summary Judgment, filed on April 30, 2001 ("Falkinham Decl."), at ¶ 6).[1] During replication, the original DNA serves as a template for the newly synthesized version. (Id.). The enzyme "DNA polymerase" carries out the DNA replication process by taking advantage of the specific chemical attraction between nucleotides as a foundation for faithful duplication. (Id., at ¶ 7). To initiate replication, DNA polymerases must recognize and bind to specific locations in the DNA. (Id., at ¶¶ 8-9). Those specific locations are marked by a very short sequence complementary to the template strand. (Id., at ¶ 8). This short sequence of complementary nucleic acid is called a "primer" strand and the DNA polymerase absolutely requires a primer strand to start replication. (Id., at ¶ 9).

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[1] The Court has used the declarations of experts that the parties have submitted to understand the technology involved in this case, but not to construe the claims. The use of expert testimony and declarations for the sole purpose of understanding the technology is permissible. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999) ("Although the patent file may often be sufficient to permit the judge to interpret the technical aspects of the patent properly, consultation of extrinsic evidence is particularly appropriate to ensure that his or her understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art.").

Similarly to DNA replication, an enzyme called RNA polymerase catalyzes the synthesis of RNA during transcription. (Declaration of Dr. Kary B. Mullis in Support of Gen-Probe Inc.'s Motion for Partial Summary Judgment of Non-Infringement under The Doctrine of Equivalents ("Mullis Decl."), at ¶ 11). Transcription begins when RNA polymerase binds to a specific starting sequence called the "promoter" sequence on the DNA. (Id., ¶ 14). Differently from DNA polymerase, RNA polymerase does not need a primer to initiate replication; it only needs a promoter sequence. (Id.). RNA polymerase then joins the ribonucleotide bases of the gene based on their complementarity to the template DNA sequence, and continues to synthesize the growing RNA chain until it reaches a termination site on the DNA where the enzyme releases the completed messenger RNA copy of the gene. (See id.). The '338 patent discloses amplification methods using replication via DNA polymerase or transcription by RNA polymerase. (E.g., '338 patent, col. 31 ln. 24 to col. 32 ln. 7).

As issued, the '338 patent contains six independent claims: claims 1, 7, 19, 27, 28, and 34. Each of these claims is generally directed to a method of, or kit for, capturing the target polynucleotide (i.e. binding a support to the target polynucleotide and substantially separating the support and bound target from the sample) and "amplifying" it. Each independent claim contains the term "amplifying." For example, claim 1 -- the broadest claim -- provides:

> A method for amplifying a target polynucleotide contained in a sample comprising the steps of:
> (a) contracting the sample with a first support which binds to the target polynucleotide;
> (b) substantially separating the support and bound target polynucleotide from the sample;
> (c) amplifying the target polynucleotide.

Steps (a) and (b) jointly disclose the "target capture" method. The '338 patent specification sets forth seven examples of the methods taught by the inventors. ('338 patent, col. 24 ln. 14 to col. 32 ln. 25). The parties do not dispute that the first three examples refer only to methods of target capture alone, while examples four through seven disclose the combination of target capture and methods of amplification. (Defendant's Statement of Disputed Facts in Opposition to Plaintiff's Motion for Partial Summary Judgment, filed on May 25, 2001 ("May 25, 2001 Statement of Facts"), at Fact 3).

C. **Gen-Probe's Transcription Mediated Amplification Method**

Gen-Probe's HIV-1/HCV Assay detects small quantities of human immunodeficiency virus ("HIV") and hepatitis C virus ("HCV") in blood by capturing the viral nucleic acids from a sample

of blood and amplifying them. (Declaration of Dr. Matthew Longiaru Filed in Support of Gen-Probe's Motion for Partial Summary Judgment of No Literal Infringement, filed April 30, 2001 ("Longiaru Decl."), at ¶ 5). This assay incorporates Gen-Probe's transcription mediated amplification ("TMA") technology to amplify the captured viral nucleic acid. (Id.).

The first step of the amplification process involves the binding of a primer to the viral RNA. The TMA amplification process employs sequence-specific primers, which are designed to bind only to specific sequences of interest in the target HIV and HCV nucleic acid. (Id., at ¶ 6). Amplification of captured nucleic acid would thus occurs only if the specific primers find and bind to their respective specific target sequences. (Id.).

The primers used in Gen-Probe's TMA process are "specific primers." (May 25, 2001 Statement of Facts, at Facts 27-28). These "specific" primers are carefully designed to bind only to a pre-selected nucleic acid sequence of a particular target organism, and precisely define the starting point of DNA replication. (Mullis Decl., at ¶ 13). Using the primer, DNA polymerase then add one base at a time in a reaction referred to as "primer extension." (See id.).

Alternatively, scientists may also use "non-specific," or "random," primers. (Falkinham Decl., at ¶ 12). Those non-specific primers usually have shorter sequences, often six nucleotides in lengths, that are likely to complementarily bind to some unspecified location on the DNA. (Id.). Once the primer is bound to the DNA, DNA polymerase then initiates the primer extension process. (Id.). Thus, when random primers are used, the resulting amplification process is referred to as "non-specific" because DNA synthesis begins at random locations anywhere on the target nucleic acid and any other nucleic acids that may be present in the samples. (Id.). The use of those "non-specific" primers avoid the work required to select, make, and test specific primers for each individual target organism. (Id.). TMA does not use non-specific primers or non-specific amplification. (May 25, 2001 Statement of Facts, at Facts 27-28).

At the second step of TMA amplification, a reverse transcriptase enzyme recognizes the primer bound to the single-stranded viral RNA and extends the primer strand by synthesizing a new DNA strand complementary to the template viral RNA. (Id., at ¶ 7). Reverse transcriptase ("RT") is a naturally occurring DNA polymerase enzyme that was first discovered in viruses. Life Techs., Inc.

v. Clontech Lab., Inc., 224 F.3d 1320, 1322 (Fed. Cir. 2000) (discussing scientific facts about reverse transcriptase enzyme). RT's polymerase activity enables it to use either DNA or RNA molecules as a template to synthesize a complementary strand of DNA. Id. In addition to DNA polymerase activity, naturally-occurring RT also exhibits RNase H that degrades RNA while not affecting DNA molecules. Id. Gen-Probe's TMA process apparently uses such form of RT. As the enzyme progresses along the RNA template, the RT's RNase activity degrades the template viral RNA, leaving only the single-stranded DNA copy. (Declaration of Scott Burwell in Support of Vysis' Opposition to Gen-Probe's Motion for Partial Summary Judgment of Noninfringement under the Doctrine of Equivalents ("First Burwell Decl."), at Exh. A, at 3-4).

At the third step, a second primer then binds to the single-stranded DNA copy. (Id.). This second primer is designed to bind on the opposite side of the region to be amplified. (Id., Exh. A, at 4). RT then synthesizes a complementary strand of DNA based on that template, resulting in a double-stranded DNA molecule. (Id., Exh. A, at 3-4).

The fourth step involves the transcription of new RNA strands by RNA polymerase enzymes based on the DNA strands generated in step two and three. (Id.). Although RNA polymerase does not necessitate a primer to initiate transcription, it requires a specific promoter sequence. (Longiaru Decl., at ¶ 8). That promoter sequence is generated when the primer binds to the target sequence in step two and three. (Id., at ¶ 9). Thus, no transcription occurs unless RT has synthesized new DNA strands from the captured viral nucleic acid. If a promoter sequence was formed, RNA polymerase binds to it and initiate transcription of the DNA sequence, resulting in a transcribed RNA copy of the template DNA strand. (First Burwell Decl., at Exh. A, at 3).

In the fifth step, one of the specific primers then binds to the newly transcribed RNA, and RT makes a new complementary DNA copy of that RNA strand. (Longiaru Decl., at ¶ 10). The process of steps one through four repeats itself in a cyclic fashion, resulting in exponential amplification of only the particular target sequence of interest. (Id.). Since each of the DNA templates can make 100-1000 transcribed copies, this expansion can result in the production of 10 billion transcribed copies in less than one hour. (First Burwell Decl., at Exh. A, at 3-4). The target sequence would then be present in sufficient amount for detection. (Id., at Exh. A, at 5).

Gen-Probe has frequently compared its TMA technology to another well-known biotechnology technique called the polymerase chain reaction ("PCR"). (E.g., Falkinham Decl., at ¶ 11; Mullis Decl., at ¶ 21). As a type of "specific" amplification," PCR uses "specific" primers to select and amplify a chosen nucleic acid sequence a billionfold. (Falkinham Decl., at ¶ 11). In its traditional form, PCR results in exponential amplification of the target nucleic acid by producing an amount of DNA that doubles in each cycle of DNA synthesis. Genentech, Inc. v. Boehringer Mannheim GmbH, 47 F. Supp. 2d 91, 99-100 (D. Mass. 1999) (providing a detailed discussion of PCR). First, the known target sequence is used to design two oligonucleotides to serve as specific primers, each one complementary to one of the two DNA strands and lying in opposite sides of the region to be amplified. Id., at 99. Those primers are then added to the reaction mixture containing the DNA to be amplified. The double-stranded DNA is then denatured by heating the mixture. Id. The first primer binds to its complementary sequence on the single strand. Id. DNA polymerase then initiates DNA synthesis starting with the primer and copies the sequence of the template strand, ultimately producing exact replicas of the target sequence. Id. After denaturation, the second, complementary primer then binds to the newly synthesized strand (at the opposite side of the region to be amplified) and provides the requisite starting point for DNA synthesis. Id. Although those two steps are described successively, they usually occur simultaneously using both strands of the template DNA as starting point. See id. The products of each duplication cycle then serves as a template for subsequent cycles, resulting in an exponential process of replication. Id. After repeated cycles of denaturation by heating and primer extension, the pool of DNA with the target sequence has been exponentially amplified. Id. Like PCR, TMA technology involves specific amplification, using specific primers, specific promoters, and specific polymerase enzymes. (May 25, 2001 Statement of Facts, at Fact 27).

An illustration of the TMA amplification process, as provided by the parties, is portrayed below. (Notice of Lodgment in Support of Plaintiff Gen-Probe Inc's Motion for Partial Summary Judgment, filed on April 30, 2001, at Exh. 7; Declaration of Scott Burwell in Support of Vysis' Opposition, filed on October 30, 2001, at Exh.A, p. 4). The steps in that illustration do not necessarily correspond to the steps described above.

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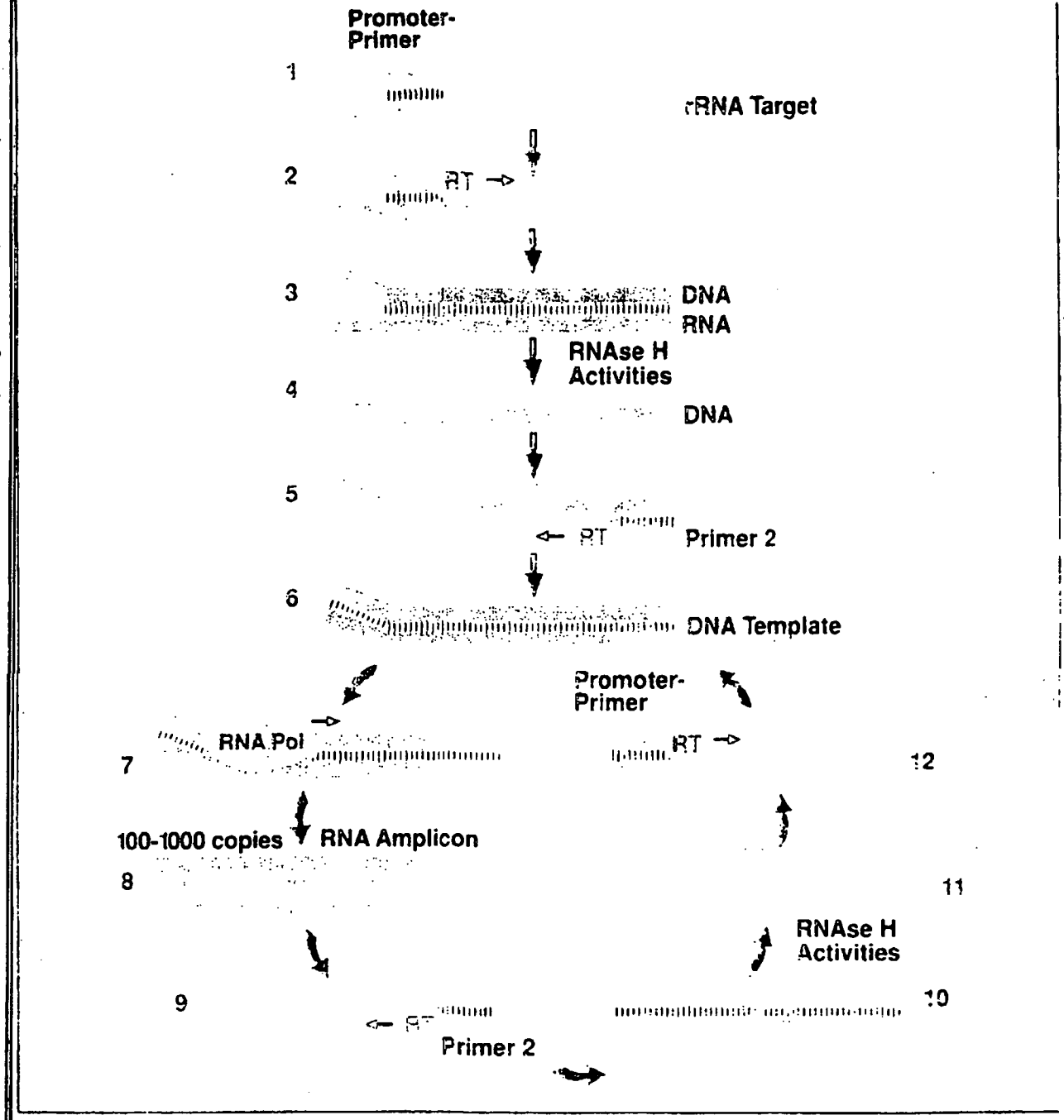

FIGURE 1. Transcription-Mediated Amplification Cycle (TMA):

Step 1: Promoter-primer binds to rRNA target.

Step 2: Reverse Transcriptase (RT) creates DNA copy of rRNA target.

Step 3: RNA:DNA duplex.

Step 4: RNAse H activities of RT degrades the rRNA.

Step 5: Primer 2 binds to the DNA and RT creates a new DNA copy.

Step 6: Double-stranded DNA template with a promoter sequence.

Step 7: RNA polymerase (RNA Pol) initiates transcription of RNA from DNA template.

Step 8: 100-1000 copies of RNA amplicon are produced.

Step 9: Primer 2 binds to each RNA amplicon and RT creates a DNA copy.

Step 10: RNA:DNA duplex.

Step 11: RNAse H activities of RT degrades the rRNA.

Step 12: Promoter-primer binds to the newly synthesized DNA. RT creates a double-stranded DNA and the autocatalytic cycle repeats resulting in a billion-fold amplification.

D. Claim Construction and Partial Summary Judgment of No Literal Infringement

On April 30, 2001, Gen-Probe filed a motion for partial summary judgment under Counts One and Three of its Second Amended Complaint arguing that its nucleic acid test for HIV and HCV does not literally infringe the claims of the '338 patent held by Vysis. Specifically, Gen-Probe argues that the '338 patent describes and encompasses only methods of non-specific amplification and that its products do not incorporate non-specific amplification.

After reviewing the papers submitted in relation to the motion and considering the parties' argument, the Court issued an order on June 20, 2001 granting Gen-Probe's motion for partial summary judgment of no literal infringement.

In that Order, the Court first construed the disputed term "amplifying." "Based on the explicit language of the specification, the repeated reference to non-specific amplification methods, and the absence of any reference to specific amplification or PCR, the Court construe[d] the term 'amplifying' as found in the claims of the '338 patent to encompass only non-specific amplification." (June 20, 2001 Order, at 10).

The Court then addressed the issue of literal infringement. The Court found that no issue of material fact existed since Vysis admitted that Gen-Probe's product uses specific amplification. (Id., at 11). "Since the Court has construed the term 'amplifying' to encompass only non-specific amplification, the Court conclude[d] that Gen-Probe does not literally infringe the claims of the '338 patent." (Id.).

II. LEGAL STANDARDS

A. Standards Controlling Motion for Reconsideration

A motion for reconsideration "is appropriate if the district court (1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." School Dist. No. 1J, Multnomah County v. ACandS, Inc., 5 F.3d 1255, 1263 (9th Cir. 1993). It is within the discretion of the district courts to grant or deny reconsideration. United States v. Desert Gold Mining Co., 433 F.2d 713, 715 (9th Cir. 1970). In addition, motions for reconsideration filed in the District Court for the Southern District of California must be submitted no later than 30 days after the entry of the challenged order. Civ. L. R.

7.1(i)(2) ("Except as may be allowed under Rules 59 and 60 of the Federal Rules of Civil Procedure, no motion or application for reconsideration shall be filed more than 30 days after the entry of the ruling, order or judgment sought to be reconsidered.").

B. Summary Judgment Standards

A motion for summary judgment shall be granted where "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). See also British Airways Bd. v. Boeing Co., 585 F.2d 946, 951 (9th Cir. 1978), cert. den., 440 U.S. 981 (1979).

Summary judgment may be appropriate when there is no genuine issue of material fact or when, drawing all factual inferences in favor of the nonmoving party, no "reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986) (stating that the purpose of summary judgment is to avoid an unnecessary trial for which there can be only one outcome). "Thus, summary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue whether the accused device is encompassed by the claims." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999).

C. Standards for Summary Judgment in Infringement Cases

Courts may grant summary judgment in patent cases. DeMarini Sports v. Worth, Inc., 239 F.3d 1314, 1331 (Fed. Cir. 2001). Specifically, courts may adjudicate patent infringement issues by summary judgment. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 n. 8 (1997) ("Where the evidence is such that no reasonable jury could determine two elements to be equivalent, [the] district court [is] obliged to grant partial or complete summary judgment....") (internal citations omitted); Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir.2001) (affirming the district court's grant of summary judgment of non-infringement).

Patent infringement analysis involves two steps. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1476 (Fed. Cir. 1998). "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993). See also

Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377, 1380 (Fed. Cir. 1999); EMI Group North America, Inc. v. Intel Corp., 157 F.3d 887, 891 (Fed Cir. 1998).

Although claim construction is a matter of law, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc), the determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). "In order for a court to find infringement, the plaintiff must show the presence of every ... [limitation] or its substantial equivalent in the accused device." Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994). "An infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents." Gart v. Logitech, Inc., 254 F.3d 1334, 1339 (Fed. Cir. 2001) (citing Bai, 160 F.3d at 1353).

D. Infringement under the Doctrine of Equivalents

"[A] product or process that does not literally infringe . . . the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co., 520 U.S. at 21. "An element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." DeMarini Sports, 239 F.3d at 1331-32.

In appropriate cases, the function-way-result test offers additional guidance on the question of equivalence. Toro Co. v. White Consol. Indus., 266 F.3d 1367 (Fed. Cir. 2001) (citing Dawn Equip. Co. v. Kentucky Farms, 140 F.3d 1009, 1015 (Fed. Cir. 1998)). Under that test, an accused device may infringe a claim under the doctrine of equivalents if it performs substantially the same overall function, in substantially the same way, to produce substantially the same overall result as the claimed invention. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950); Unidynamics Corp. v. Automatic Prod. Int'l, Ltd., 157 F.3d 1311, 1322 (Fed. Cir. 1998) (citing Alpex Computer Corp. v. Nintendo Co., 102 F.3d 1214, 1222 (Fed. Cir. 1996)); Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934 (Fed. Cir. 1987) (in banc), cert. denied, 485 U.S. 961 (1988). The analysis

of insubstantiality under this "function-way-result" test "should be applied as an objective inquiry on an element-by-element basis." Warner-Jenkinson, 520 U.S. at 40.

The inquiry into the insubstantiality of the differences need not occur if a claim limitation is completely missing from the accused device. Warner-Jenkinson, 520 U.S. at 33-34; Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934-35, 939 (Fed. Cir. 1987) (en banc). In fact, the doctrine of equivalents is inapplicable where it would vitiate a clear structural limitation recited in the claims. See Sage Products, Inc. v. Devon Industrial, Inc., 126 F.3d 1420, 1425 (Fed. Cir. 1997) (finding that there can be no infringement under the doctrine of equivalents if the accused infringer "achieves the same result . . . but does so by a different arrangement of the elements."); Dolly, Inc. v. Spalding & Evenflo Companies, Inc., 16 F.3d 394, 398 (Fed. Cir. 1994) (finding that, where the claim only calls for one structure but the accused device uses two separate elements to create that structure, the doctrine of equivalents could not apply).

Besides the issue of insubstantiality of the differences, there are further limits to the application of the doctrine of equivalents. For instance, there is no infringement by equivalents if the asserted scope of equivalency would encompass the prior art. Marquip, Inc. v. Fosber Am., Inc., 198 F.3d 1363, 1367 (Fed. Cir. 1999); Wilson Sporting Goods v. David Geoffrey & Assoc., 904 F.2d 677, 683 (Fed. Cir. 1990). Moreover, prosecution history estoppel can bar a patentee from invoking the doctrine of equivalents when the patentee has relinquished subject matter during the prosecution of the patent through amendment or argument. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558 (Fed. Cir. 2000) (en banc), cert. granted, 121 S. Ct. 2519 (2001); Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373, 1376-77, 50 USPQ2d 1033, 1036 (Fed. Cir. 1999).

III. DISCUSSION

A. Vysis' Motion for Reconsideration of the Court's Interpretation of "Amplifying"

The first step in any infringement analysis is the construction of the claim terms at issue. Wang Laboratories, 197 F.3d at 1380. The disposition of the partial summary judgment motion hinges on the definition of the term "amplifying" as used in the claims of the '338 patent. In its June 20, 2001 Order, the Court has already expressly defined that term "to encompass only non-specific amplification." (June 20, 2001 Order, at 10).

However, Vysis dedicates most of its Opposition and over half of its Supplemental Opposition brief to disputing that construction and requesting a reconsideration of that ruling. (Vysis' Opposition, at 6-18 ("Indeed, the Court's prior ruling on the literal scope of the '338 patent claims should be reconsidered ...." (Id., at 7)); Vysis' Supplemental Opposition, at 1-6 ("This testimony is further reason for the Court to reconsider its earlier claim construction ruling." (Id., at 3)). First, Vysis argues that the Court has improperly read into the patent claims a limitation from the patent specification. To support that proposition, it relies heavily on three recent cases from the Federal Circuit: Dayco Prods., Inc. v. Total Containment, Inc., 258 F.3d 1317, 1327 (Fed. Cir. 2001), Gart v. Logitech, Inc., 254 F.3d 1334 (Fed. Cir. 2001), and Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323 (Fed. Cir. 2001). Second, Vysis marshals text in the '338 patent specification and language in the prosecution history to support its contention that the word "amplifying" encompasses specific amplification as well as non-specific amplification. Third, Vysis points to extrinsic evidence -- including expert testimony -- that have become available since the Court's June 20, 2001 Order to buttress its preferred claim construction.

Having considered Vysis' motion, the Court denies Vysis' request for reconsideration. As explained below, that request is untimely under the local civil rules, inadequate under the law controlling reconsideration, and unsupported by the substantive patent law as explained by the Federal Circuit.

1. Vysis' Reconsideration Request Is Untimely

At the threshold, the Court must first determine whether Vysis' request for reconsideration is timely and proper. In its papers, Vysis argues that the June 20, 2001 Order was based on an error in claim construction, and that the Court can revise that order under Fed. R. Civ. P. 54(b).

It is true that courts have the inherent power to modify their interlocutory orders before entering a final judgment. Marconi Wireless Telegraph Co. v. United States, 320 U.S. 1, 47-48 (1943); John Simmons Co. v. Grier Brothers Co., 258 U.S. 82, 88 (1922); Balla v. Idaho State Bd. of Corrections, 869 F.2d 461, 465 (9th Cir. 1989). In addition, the Federal Rules of Civil Procedure

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explicitly grant federal courts the authority to modify their interlocutory orders. Fed. R. Civ. P. 54(b) (stating that any order which is not certified under Rule 54(b) and which adjudicates fewer than all the claims as to all the parties "is subject to revision at any time before the entry of [final] judgment").

However, once an order is entered, a court can set it aside only through a Rule 60(b) motion or a motion for reconsideration. Ground v. Sullivan, 785 F. Supp. 1407, 1410 n.3 (S. D. Cal. 1992) ("Once an order of the court is entered, the judge can set aside or change it either through a Rule 60 motion or a motion for reconsideration pursuant to Local Rule 7.1(i)."") (citing Schwarzer, Tashima, & Wagstaffe, Cal. Prac. Guide: Fed. Civ. Pro. Before Trial § 12:157 (TRG 1991)). Under the facts of this case, Vysis cannot rely on Rule 60(b) since it cannot show "mistake, inadvertence, surprise or excusable neglect" to support its request. See Fed. R. Civ. P. 60(b). Rather, its request relies on an alleged error in claim construction. Hence, Vysis can only seek relief from the June 20, 2001 Order through a motion for reconsideration, and the Court will consequently construe Vysis' request as such.

The motion for reconsideration is, however, not timely. The Southern District of California's Local Rule 7.1(i)(2) places a thirty-day limit on such motions. Civ. L. R. 7.1(i)(2) ("Except as may be allowed under Rules 59 and 60 of the Federal Rules of Civil Procedure, no motion or application for reconsideration shall be filed more than 30 days after the entry of the ruling, order or judgment sought to be reconsidered."). Vysis has filed the papers containing this request for reconsideration on October 30, 2001, despite the fact that the Court entered the challenged order on June 20, 2001. Over four months elapsed between the Court's June 20, 2001 Order and Vysis's request, thereby placing the reconsideration motion outside of the thirty-day limit provided by the local rules.

It is within the discretion of the district courts to grant or deny reconsideration. Desert Gold Mining Co., 433 F.2d at 715. The long delay, supplemented by Vysis' covert attempt to request reconsideration through its opposition papers, leads the Court to exercise its discretion in denying reconsideration.

In any case, even if the Court were to grant reconsideration, Vysis' arguments would be unavailing. For the sake of completeness, the Court will discuss the flaws in Vysis' contentions below.

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2. **Reconsideration Based on an Intervening Change in Controlling Law**

a. **No Change in Controlling Law Has Occurred**

A motion for reconsideration "is appropriate if the district court (1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." School Dist. No. 1J, 5 F.3d at 1263. Vysis' first basis for reconsideration is an alleged change in controlling law, based on Dayco Prods., Inc. v. Total Containment, Inc., 258 F.3d 1317 (Fed. Cir. 2001), Gart v. Logitech, Inc., 254 F.3d 1334 (Fed. Cir. 2001), and Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323 (Fed. Cir. 2001).

However, none of those cases affected the controlling law. Rather, all three cases merely apply a known rule in patent law. They illustrate the basic principle that, in construing claims, courts may not read a superfluous limitation into a claim from the written description. Dayco Prods., 258 F.3d at 1324-27 (finding error in the construction of four claim terms because the district court improperly imported limitations from the specification into the claims); Interactive Gift Express, 256 F.3d at 1333-34 (holding, inter alia, that the district court's exclusion of a buyer's home as a "point of sales location" based on the written description was reversible error because the claims did not preclude that possibility and other parts of the specification indicated that a home could be such a location); Gart, 254 F.3d at 1341-43 (finding that the district court improperly required that the claim term "angular medial surface" includes a "ledge," because "the written description does not explicitly limit the subject matter of the patent to the ledge configuration set forth in the drawings.").

It is well-settled in patent law that it is improper to import into a claim a limitation from the specification's general discussion, embodiments, and examples. E.g., Enercon GmbH v. International Trade Comm'n, 151 F.3d 1376, 1384 (Fed. Cir. 1998); Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1578 (Fed. Cir. 1996); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1278 (Fed. Cir. 1995); Genentech, Inc. v. The Wellcome Foundation Ltd., 29 F.3d 1555 (Fed. Cir. 1994); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed. Cir. 1993); Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 836 (Fed. Cir. 1991); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988). Accordingly, no change in controlling law has occurred, and none of Vysis' cited cases provide it with the requisite grounds for reconsideration.

b. Courts May Look to the Written Description for Claim Construction

Even on the merits, Vysis' argument that the Court improperly imported a superfluous limitation into the claims would fail. In pointing to the cases above, Vysis essentially argues that the Court ought to interpret the disputed claim term without consulting the specification. The Court cannot, however, adopt Vysis' argument. Gart, 254 F.3d at 1341 (stating that "claims do not have meaning removed from the context from which they arose, i.e., 'the claims are directed to the invention that is described in the specification.'") (quoting Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001)).

First, although it is true that the Federal Circuit has reversed Gart, Interactive Gift, and Dayco based on claim constructions that were too narrow, those facts do not easily transfer to the present matter. The technologies and patent documents between this pending matter and those cases are very different. This case involves biotechnology, while Gart focused on an ergonomic computer mouse, Interactive Gift dealt with information control systems, and Dayco related to flexible hoses for use in underground gas containment systems. The claim construction in each of those three cases necessarily depended on the particular technology, the specific disputed claim terms, and the disclosure that the patentees made in the written description. What the Federal Circuit found improper in those cases would not necessarily be erroneous here. Indeed, "[a]ll rules of construction must be understood in terms of the factual situations that produced them, and applied in fidelity to their origins." Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996). Consistent with that principle, the Court must construe the claims based on the '338 patent and look at Gart, Interactive Gift, and Dayco as merely illustrative of the rule for which they stand.

Second, the rule of construction that Vysis emphasizes in its papers is not dispositive of this case. Although courts may not import a limitation from the specification into the claims, judges must read the claims in view of the specification and therefore may look to the written description to define a term already in a claim limitation. Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). "These two rules lay out the general relationship between the claims and the written description. As rules at the core of claim construction methodology, they provide guideposts for a spectrum of claim construction problems." Id. (citations omitted).

The interaction of those two canons creates a fine line for the Court and the parties to walk: "It is entirely proper to use the specification to interpret what the patentee meant by a word or a phrase in the claim. But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." E.I. du Pont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988) (citation omitted). To avoid improperly crossing this line, a party wishing to use statements in the written description to confine a patent's scope must first point to a term in the claim with which to incorporate those statements. Renishaw, 158 F.3d at 1248. In other words, "a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description." Id. See also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the specific definition of the term is clearly stated in the patent specification or file history.").

Where such term exists, the Court should refer to the written description to decipher the meaning that the patentees intended to give to that term. In general, absent a special and particular definition created by the patent applicant, terms in a claim are to be given their ordinary and accustomed meaning. York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996) ("Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning."). But, where the "patent applicant has elected to be a lexicographer by providing an explicit definition in the specification for a claim term[,] the definition selected by the patent applicant controls." Renishaw, 158 F.3d at 1249. In such instance, courts must turn to the written description to construe the disputed term.

In this case, Gen-Probe has pointed to the claim term "amplifying" as a word in need of interpretation. As always, the court start its claim construction with a careful examination of the words of the patent claims. As the Court previously explained, "[t]he claim language in this case does not help determine the construction of the term 'amplifying.' The term 'amplifying' is found in each of the principle [sic] claims without any modification." (June 20, 2001 Order, at 5). Neither the doctrine of claim differentiation nor any qualifier to the disputed word elucidates whether this claim term only refers to non-specific amplification.

Normally, where the text of the claims does not indicate a particular meaning, the rules of claim construction would give that word its ordinary and accustomed meaning. York Prods., 99 F.3d at 1572. However, the patentees here chose to be their own lexicographers by defining the word "amplify" in the written description. ('338 patent, col. 2, ln. 9-19). Because of the patentees' choice, the Court must follow Federal Circuit rules and interpret that term in light of the disclosure made by the patentees in their specification.

The Court will give that term the meaning that the patentees intended in the written description, even if that meaning is more restrictive than the ordinary definition of that word. See Slimfold Mfg. Co. v. Kinkead Indus., Inc., 810 F.2d 1113, 1116 (Fed. Cir. 1987) ("Claims are not interpreted in a vacuum, but are part of and are read in light of the specification."). The Court is not improperly importing a limitation into the claims as Vysis contends, but it is rather complying with Federal Circuit law and giving effect to the correct meaning of that disputed claim term by looking to the specification. Renishaw, 158 F.3d at 1250 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."). Consequently, Vysis' first argument on reconsideration would have failed on the merits.

3. Reconsideration Motion Based on The Specification and Prosecution History

Anticipating the failure of its first argument, Vysis then contends -- as a second ground for reconsideration -- that (1) the '338 patent specification does not exclude specific amplification techniques, and that (2) the prosecution history demonstrates that specific amplification is within the scope of the claims. These contentions are improper grounds for reconsideration, and would fail on their merits if the Court granted reconsideration.

a. No New Fact Has Been Presented To Support Reconsideration

A party may seek reconsideration for "clear error or [where] the initial decision was manifestly unjust ...." School Dist. No. 1J, 5 F.3d at 1263. In addition to showing error or injustice, the party must show the Court "what new or different facts or circumstances are claimed to exist which did not exist, or were not shown upon such prior application." Civ. L. R. 7.1(i)(1). By alleging that the Court

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improperly reviewed the specification and prosecution history, Vysis appears to base its second ground for reconsideration on this claim of error and injustice.

However, Vysis has failed to meet the requirements for reconsideration. Instead of offering new arguments, facts or circumstances as required by law and the local rules, Vysis has done no more than copy paragraphs from its opposition to Gen-Probe's first motion for partial summary judgment, and submit them in its current opposition papers with little or no change. Compare Vysis' May 25, 2001 Opposition, at 8:2-10:8 and Vysis' October 30, 2001 Opposition, at 10:20-12:25. Compare also Vysis' May 25, 2001 Opposition, at 4:10-7:15 and Vysis' October 30, 2001 Opposition, at 13:4-16:9. This "cut and paste" approach does not meet the requirements under the law and the local rules for reconsideration.

b. The Written Description and the File Wrapper Limit "Amplifying" to Non-Specific Amplification

Even if the Court were to grant reconsideration, it would deny Vysis' motion on the merits. In its arguments related to this second ground for reconsideration, Vysis contends that the specification permits the Court to interpret "amplifying"as encompassing specific amplification techniques, and that the prosecution history demonstrates that specific amplification is within the scope of the claims. The Court disagrees.

The words in a patent claim are to be given their ordinary meaning, unless inconsistent with the specification and prosecution history. Desper Products, Inc. v. Qsound Labs, Inc., 157 F.3d 1325, 1336 (Fed. Cir. 1998). As discussed above, the Court must construe the disputed claim term in light of the specification because the patentees have chosen to be his own lexicographers. See Part III.A.2.b supra. In looking to the written description to give meaning to the claim term, the Court must interpret that term consistently with the specification, because the specification explains the nature of the patentees' invention. Renishaw, 158 F.3d at 1250. As the Federal Circuit explained in Renishaw:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the

correct construction. A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.

Id. (citations omitted). "Although the specification need not present every embodiment or permutation of the invention and the claims are not limited to the preferred embodiment of the invention, neither do the claims enlarge what is patented beyond what the inventor has described as the invention." Netword, 242 F.3d at 1352 (citing Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998)). Here, the written description and the file wrapper clearly indicate that the invention disclosed to the public is the combination of target capture and non-specific amplification.

i). The Written Description Only Teaches Non-Specific Amplification

The word "amplify" first appears in the "Background of the Invention" section. ('338 patent, col. 2, ln. 9-19).[2] That passage suggests a broad denotation of the disputed term, indicating that it means "creating an amplification product ...." That definition does not, however, elucidate whether the term should encompass specific amplification. In fact, it does not mention or insinuate anything about the type of amplification contemplated by the inventors. The Court must then look beyond that passage to other parts of the specification to discern the scope of the invention. United States v. Adams, 383 U.S. 39, 49 (1966) ("Claims are to be construed in light of the specifications and both are to be read with a view to ascertaining the invention.").

Most of the remainder of the written description discusses and discloses the capture techniques. ('338 patent, col. 4 ln. 19 to col. 30 ln. 14). In that large passage, a few occasional mentions of the words "amplify" or "amplification" occurs. (Id., at col. 9, ln. 48-49; col. 9, ln. 61; col. 15, ln. 41; col. 15, ln. 56-58; col. 16, ln. 3-4; col. 16, ln. 10-13; col. 16, ln. 17-22; col. 18, ln. 8; col. 18, ln. 10-16; col. 18, ln. 59). Most of these occasional mentions, however, merely indicate that an amplification step may follow the capture steps. (E.g., id., at col. 9, ln. 48-49; col. 15, ln. 56-58; col. 18, ln. 8; col. 18,

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[2] "The term 'amplify' is used in the broad sense to mean creating an amplification product which may include by way of example, additional target molecules, or target-like molecules which are capable of functioning in a manner like the target molecule, or a molecule subject to detection steps in place of the target molecule, which molecules are created by virtue of the presence of the target molecule in the sample. In the situation where the target is a polynucleotide, additional target, or target-like molecules, or molecules subject to detecting can be made enzymatically with DNA or RNA polymerases or transcriptases." ('338 patent, col. 2, ln. 9-19.)

ln. 10-16; col. 18, ln. 59). The remainder arise in the description of the figure illustrating one of the preferred embodiments of the invention. (Id., at col. 9, ln. 61; col. 15, ln. 56-58; col. 16, ln. 3-4; col. 16, ln. 10-13; col. 16, ln. 17-22).

It is noteworthy that, when the term "amplify" arises in the illustrated preferred embodiment, the descriptions focuse on non-specific amplification. (See col. 15, ln. 56-58 ("In Step 3 of FIGS. 4, 5, and 6, the isolated target is **non-specifiably** [sic] amplified to form a multitude of amplification products."); col. 16, ln. 10-13 ("FIG. 5 illustrates the application of a two enzyme amplification system. In Step 3(a) of FIG. 5, DNA polymerase is used in conjunction with [random] **hexamer primers** to generate DNA segments which are complementary to the target."); col. 16, ln. 17-22 ("FIG. 6 illustrates the application of an enzymatic amplification system based on the enzyme DNA polymerase. Thus, in step 3(a), the target, separated from extraneous polynucleotides, impurities and debris, is subjected to DNA polymerase in conjunction with **non-specific hexamer primers**.")) (emphasis added). Although the illustrations of the preferred embodiments are not sufficient to restrict the scope of the claim, Dayco, 258 F.3d at 1328 ("[I]t is not proper to treat characteristics of a preferred embodiment as claim limitations."), the Court may nonetheless consider them in its claim interpretation. Markman v. Westview Instruments, 52 F.3d 967, 979-980 (Fed. Cir. 1995) ("[C]laims must be read in view of the specification, of which they are a part."), aff'd, 517 U.S. 370 (1996).

The '338 patent provides a greater discussion of the "amplification" technique toward the end of written description. ('338 patent, col. 30 ln. 14 to col. 32 ln. 25). Immediately before the Examples that discloses amplification in the '338 patent, the inventors set forth their teachings with respect to methods of amplification:

> The sensitivity of the above DNA or RNA target capture methods can be enhanced by amplifying the captured nucleic acids. This can be achieved by **non-specific replication** using standard enzymes .... In addition, where amplification is employed following purification of the target nucleic acids as described above, the amplified nucleic acids can be detected according to other, conventional methods not employing the [techniques] described above. Amplification of the target nucleic acid sequences, because it follows purification of the target sequences can employ **non-specific**

> **enzymes or primers** (i.e. enzymes or primers which are capable of causing the replication of virtually any nucleic acid sequence). Although any background, non-target nucleic acids are replicated along with target, this is not a problem because most of the background nucleic acids have been removed in the course of the capture process. Thus **no specially tailored primers are needed** for each test, and the same standard amplification reagents can be used regardless of the targets.

('338 patent, col. 30, lines 14-40) (emphasis added). This passage introducing the amplification techniques only addresses the possibility of using non-specific amplification methods.

Vysis argues that the passage's language is permissive, allowing the use of specific amplification in addition to the non-specific amplification disclosed in the quoted passage and in Examples 4-6. The Court disagrees. The passage does not teach any benefit from the combination of target capture and specific amplification. Rather, it emphasizes the use of non-specific amplification. For instance, after explaining that amplification can increase the sensitivity of the capture methods, the patent states that "[t]his can be achieved by **non-specific** replication using standard enzymes (polymerases and/or transcriptase)." (Id., col. 30, ln. 14-18) (emphasis added). In addition, the patent underscores that, after the capture step, "no specially tailored primers **are needed** for each test, and the same standard amplification reagents can be used, regardless of the targets." (Id., col. 30, ln. 38-40) (emphasis added). In other words, the patent asserts that the specific primers are superfluous thanks to the capture step, allowing the practitioner to use the same reagents to amplify any type of nucleic acid targets. The patent was thus teaching away from the use of specific amplification. The language was not permissive, but rather preclusive.

Vysis further submitted in its Supplemental Opposition snippets of Dr. Mullis' deposition testimony to support the idea that the passage divulges permissive rather than exclusive language. (Vysis' Supplemental Opposition, at 4-5). But, it is to no avail. First, Dr. Mullis was interpreting his own patent and publications -- not the '338 patent -- when he was asked about his construction of permissive language. He was testifying as the inventor of his own patent and author of his own published articles, differently from his role as expert witness that he would have in this case. Second, claim construction is a legal issue reserved exclusively for the Court, not for an expert witness. See

Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). Dr. Mullis' comments in this context certainly would constitute extrinsic evidence, rather than an explanation of the technology, upon which the Court may not rely. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309, (Fed. Cir. 1999). Therefore, the Court finds that this passage's language precludes, rather than permits, the use of specific amplification.

Despite this clear limitation, Vysis nonetheless states that the patent does not describes the conceived amplification techniques because the patent focuses on the combination of amplification and capture methods. Again, the Court disagrees. Despite what Vysis asserts, there are three examples that actually address amplification after capture. Those three examples -- Examples 4 to 6 -- only discuss non-specific amplification. Example 4 teaches the use of RNA polymerase to amplify captured target DNA. ('338 patent, col. 30 ln. 42 to col. 31 ln. 20). But, as the parties agree, the example exclusively focuses on non-specific amplification of the resulting transcribed product. (May 25, 2001 Statement of Facts, at Fact 7). See also '338 patent, col. 31, ln. 14-17 ("The resulting **non-specific** transcription of the target DNA produces many RNA transcripts of the target DNA which are then captured ....") (emphasis added)).

Example 5 similarly restricts its teaching to nucleic acid amplification using non-specific replication followed by amplification by transcription of the captured DNA. (Id., col. 31, ln. 24-54). As Example 5 explains, "[i]n this example both **non-specific** replication of target DNA and transcription of that DNA are used to amplify capture target DNA." (Id., col. 31, ln. 25-27). The example underscores its use of non-specific primers since it expressly uses "random oligohexamer primers" that are non-specific primers for replication of the target DNA. It further states that "[b]ecause the primers are **random**, some will, simple as a matter of statistics, bind to and cause replication of sample sequences, no matter what those sequences are." (Id., col. 31, ln. 31-32; and col. 31, ln. 45-47) (emphasis added). The example is thus replete with references to non-specificity.

Likewise, example 6 teaches how to non-specifically replicate the target DNA using DNA polymerase. (Id., col. 31 ln. 44 to col. 32 ln. 7). As the example explains, the polymerase is added to the reagents "to bring about non-specific double-stranded DNA syntheses." (Id., col. 31, ln. 63-64). The parties do not dispute that Example 6 discloses only non-specific amplification. (May 25, 2001

Statement of Facts, at Fact 11). In sum, the examples addressing amplification only disclosed non-specific amplification.

In spite of this abundance of evidence pointing to the exclusive disclosure of non-specific amplification, Vysis hangs its hopes on a parenthetical sentence in Example 5.[3] The sentence at issue states: "(Alternatively, the double stranded DNA can be formed by synthesis starting from capture probe a.)" (Id., col. 31, ln. 47-49) (parentheses in original). Vysis contends that the parenthetical disclosure indicates that the capture probe is used as a specific primer to the target DNA and thus discloses "specific amplification."

The Court declines to adopt Vysis' contention because the context surrounding that example only discusses non-specific amplification, and the parenthetical does not teach specific amplification to one of skill in the art. As explained above, the specific language of Example 5 refers only to amplification initiated by using non-specific random hexamers. Moreover, Example 5 incorporates Figure 5, of the drawings in the patent. In discussing Figure 5, the inventors state, "In Step 3 of FIGS. 4, 5 and 6, the isolated target is **non-specifically** amplified to form a multitude of amplification products." (Id., col. 15, ln. 56-58) (emphasis added). Clearly, Example 5 only addresses non-specific amplification, and contradicts Vysis' argument. See Dayco, 258 F.3d at 1324 ("If an argument offered in support of a particular claim construction is so convoluted and artificial that it would not be apparent to a skilled artisan reading the patent and the prosecution history, the argument is simply unhelpful to the performance of our task.").

More saliently, the skilled artisan in this field of science would not read Example 5's parenthetical sentence as referring to specific amplification. The "capture probe a" is a polynucleotide single strand that includes a ligand bound to the surface support and that is capable of binding to its complementary sequence on the target nucleic acid. ('338 patent, col. 15, ln. 46-51). The capture probe may bind to the target nucleic acid and may provide, under the proper orientation and

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[3] In addition to dedicating a substantial portion of its opposition brief to arguing this point, Vysis reiterates the argument in its supplemental opposition brief by presenting Dr. Mullis' deposition statements that "capture probe a" is a specific primer. (Vysis's Supplemental Opposition, at 3). The Court, however, declines to consider those deposition statements since they constitute extrinsic evidence contradicting the plain meaning of the claims and thus inadmissible in claim construction. Vitronics, 90 F.3d at 1583. Moreover, as explained in the following paragraphs, that "capture probe a" is a "specific" primer does not lead one of skill in the art to use "specific amplification" given the particular disclosure in Example 5.

conditions, the necessary primer for DNA polymerase to start DNA replication. But, as described in Example 5, the primer **only** enables the synthesis of the complementary strand to the target sequence, resulting in a double-stranded chain. (Id., col. 31, ln. 27-48). The primer does not mediate the amplification of the DNA template; this amplification is left to the RNA polymerase to produce RNA copies of the double-stranded DNA. (Id., col. 31, ln. 48-53). Specific amplification requires the involvement of the polymerase enzyme and the specific primers, working in a coordinated way to make additional copies of the template sequence. For example, in each round of PCR amplification, a specific primer must bind to a template strand and provide the initiation site for DNA polymerase to start copying the template. In Example 5, Vysis' purported "specific primer" only mediates the synthesis of the complementary strand to the original template target nucleic acid. It has no further role in the subsequent copying and amplification of the original target nucleic acid. The production of a single complementary strand can hardly be regarded as true "amplification."

Without any particular text in the specification upon which to base its specific amplification argument, Vysis submits that the term "amplifying" was always used and meant to be used in its broadest sense, and thus covers both specific and non-specific amplification. That contention runs contrary to the written description's disclosure. First, there is no discussion -- or even mention -- in the patent's written description of PCR, one of the best known form of specific amplification. The only mention of specific amplification actually teaches away from using specific primers and specific amplification. ('338 patent, col. 30, ln. 38-40 ("no specially tailored primers **are needed** for each test, and the same standard amplification reagents can be used, regardless of the targets.") (emphasis added)). Second, this argument ignores the overwhelming evidence that the specification exclusively describes non-specific amplification. As the Federal Circuit has recognized, "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1341 (Fed. Cir. 2001). See also Watts v. XL Sys., Inc., 232 F.3d 877, 882 (Fed. Cir. 2000); Cultor Corp. v. A.E. Staley Manufacturing Co., 224 F.3d 1328 (Fed. Cir. 2000); Wang Labs, 197 F.3d at 1382-83; Toro Co. v. White

Consolidated Industries, Inc., 199 F.3d 1295 (Fed. Cir. 1999); O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1581 (Fed. Cir. 1997).

The discussion of two of those cases will suffice to underscore how this line of precedent applies to this case. In Toro, the Federal Circuit construed a claim requiring a "cover **including** [a ring]" to mean that the ring structure is permanently attached to the cover. Toro, 199 F.3d at 1302 (emphasis added). As in this case, the disputed term "including" ordinarily has permissive connotations. Yet, the court of appeals read the claim in light of the specification and found that "[t]he specification shows only a structure whereby the restriction ring is 'part of' the cover ... This is not simply the preferred embodiment; it is the only embodiment." Id., at 1301 (noting also that "[n]owhere in the specification, including its twenty-one drawings, is the cover shown without the restriction ring attached to it."). As in Toro, the '338 patent's specification -- including the drawings -- only show methods involving non-specific amplification. The proper interpretation of the claim term in light of the specification requires restricting "amplifying" to non-specific amplification.

In Wang Labs, the Federal Circuit determined that, although the term "frame" had meaning in general usage that encompassed both bit-mapped and character-based protocols, the specification only described and taught character-based display frames. Wang Labs, 197 F.3d at 1382-83. Thus, the court of appeals limited the claims to the only teaching set forth in the embodiment. In reaching its conclusion, the Federal Circuit held that claims should not be interpreted to have a meaning or scope that would lead to their invalidity. Wang Labs, 197 F.3d at 1383. The court of appeals held that the requirements of 35 U.S.C. § 112 could not be met with respect to protocols other than character-based frames. Id.

In this case, a motion for invalidity pursuant to 35 U.S.C. § 112 is not before the Court. However, the specification of the '338 patent does not describe specific amplification methods and does not teach any benefit from the combination of target capture and specific amplification. Title 35 U.S.C. section 112, paragraph 1 of the Patent Act requires that a patent specification describes an invention in sufficient detail that one skilled in the art can reasonably conclude that, as of the filing date, the inventors were in possession of the claimed invention. Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). "It is a truism that a claim need not be

limited to a preferred embodiment. However, in a given case, the scope of the right to exclude may be limited by a narrow disclosure." Gentry Gallery v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998) (limiting the broad claims to a particular embodiment disclosed in the specification by virtue of the written description requirement). As discussed above, the specification exclusively teaches the use of non-specific amplification. It does not disclose to one of skill in the art that the inventors possessed the combination of capture methods and specific amplification. The Court finds it difficult to construe "amplifying" to include specific amplification based on the specification's disclosures in a manner that would satisfy the written description requirement of 35 U.S.C. § 112.

"Claim construction" is the judicial statement of what is and is not covered by the technical terms and other words of the claims. United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997). Having carefully reviewed the specification, the Court concludes that the specification supports Gen-Probe's contention that the term "amplifying" as used in the '338 patent only includes non-specific amplification.

ii). The Prosecution History Supports The Adoption of Non-Specific Amplification

"When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1472, 1478 (Fed. Cir. 1998). As shown above, the specification overwhelmingly indicates that the term "amplifying" only referred to non-specific amplification. This would normally ends the inquiry.

But for the sake of completeness, the Court will also consider the prosecution history. In general, courts should review the file wrapper during claim construction because the public has a right to rely on statements made by the patent applicant or his attorney during prosecution that define the scope of the claims. Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997). Specifically, arguments and amendments made during prosecution of a patent application limit claim terms so as to exclude any interpretation that was disclaimed during prosecution. Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995), cert. denied, 516 U.S. 987 (1995).

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To buttress its case, Vysis contends that the prosecution history clearly indicates that both the patent owner and the Patent and Trademark Office ("PTO") considered the claimed invention to include PCR, a type of specific amplification. First, Vysis points to a response by the patentees to the PTO, indicating that "[t]argets can be amplified by a number of ways including PCR." (May 25, 2001 Declaration of Thomas Banks in Support of Vysis' Opposition to the Gen-Probe's Motion for Partial Summary Judgment ("First Banks Decl."), Exh. E, at 124). Second, the examiner's Statement of Reasons for Allowance states that "[t]he claims are drawn to methods of PCR amplification wherein the target is first separated from the sample by using a support that binds to the target polynucleotide and then amplified." (Id., Exh. F, at 129). Third, Vysis argues that, when the patent application was initially filed, the PTO understood the '338 patent to include specific amplification techniques, mainly because the PTO rejected the original claims as obvious in light of the PCR patents. The Court finds neither of these arguments to be convincing.

First, Vysis cannot expand the scope of its patent by assigning a new and broader meaning to the claims in the course of patent prosecution. The office action response upon which Vysis relies was made in December 1995. (Id., Exh. E, at 126). In other words, the assertion that the patent encompasses PCR first occurred eight years after the original patent application was filed and in support of the fourth continuation application on the invention at issue. (Id., Exh. E, at 107 and 111-13). It is clear that this assertion was a post-facto argument since the patent's specification contains no mention of PCR or specific amplification. It is more likely that, during those eight years, Vysis saw science evolve prodigiously and realized that specific amplification is superior to non-specific amplification when combined with target capture.

Patent law does not support the use of belated prosecution arguments to retroactively change the scope of the claims. The Federal Circuit has often rejected patent owners' attempt to use prosecution history to justify a broader definition of the claim term than the specification can justify. See Multiform Desiccants, 133 F.3d at 1478 (affirming the district court's refusal to accept a dictionary definition giving broad scope to a claim term that was submitted by a patentee during prosecution after the patentee became aware of a competitor's device); Eastman Kodak Co. v. Goodyear tire & Rubber Co., 114 F.3d 1547, 1556 (Fed. Cir. 1997) ("To the extent that the examiner's

[reexamination] certificate purports to ascribe meaning not found in the claim language, this court must not permit prosecution history evidence to 'enlarge, diminish, or vary' the meaning of claim language."), limited on other grounds, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998) (en banc). As the Federal Circuit explained, "when a claim term understood to have a narrow meaning when the application is filed later acquires a broader definition, the literal scope of the term is limited to what it was understood to mean at the time of filing." Kopykake Enters. v. Lucks Co., 264 F.3d 1377, 1383 (Fed. Cir. 2001) (citing Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352-54 (Fed. Cir. 2000)). The time of filing is the date of the original patent application: December 21, 1987. (First Banks Decl., Exh. E, at 113). The best evidence for a contemporary understanding of patent is the specification, since it had to sufficiently teach one of skill in this art how to use the invention and inform the skilled artisan that the inventors were in possession of the claimed invention. See 35 U.S.C. § 112. As discussed above, the specification clearly indicates that the invention, at the time of filing, only encompassed non-specific amplification. Consequently, the Court declines to accept Vysis' invitation to broaden the claim's scope based on its patent attorney's belated statement.

Second, the patent examiner's Statement of Reasons for Allowance does not change the Court's analysis. The examiner made that statement in October 1997, close to ten years after the patent was originally filed. That belated statement is unpersuasive since the Court must construe the patent from the vantage of the skilled artisan reading the patent at the time of filing, not ten years later. Schering Co., 222 F.3d at 1353 ("[T]his court must determine what the term meant at the time the patentee filed the [patent] application); Eastman Kodak, 114 F.3d at 1555 ("As a general rule, the construing court interprets words in a claim as one of skill in the art at the time of invention would understand them."). In addition, in light of the specification and the rest of the prosecution history, the Court cannot accept the examiner's belated statement as controlling. See Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1155 (Fed. Cir. 1997) ("In light of the overall prosecution history of the ... patent, however, that single remark is not sufficient to justify importing a qualification into the plain language of the claim, especially since the remark was not in a statement made by the applicants, but rather appeared in the examiner's characterization of the applicants' claimed invention.").

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Third, even if the PTO and its examiners understood the patent as Vysis contends, the patentee cannot leverage the prosecution history to broaden the scope of narrow claims. Rather than expand the claims' scope, "[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., 54 F.3d at 1576. See also Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) ("[T]he prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance."). As the Federal Circuit emphasized, "[a]lthough the prosecution history can and should be used to understand the language used in the claims, it too cannot 'enlarge, diminish or vary' the limitations in the claims." Markman, 52 F.3d at 979. (citations omitted). Yet, Vysis attempts to vary and enlarge the scope of the term "amplifying," by using the prosecution history. In light of the Federal Circuit's precedent, the Court is without power to do so.

Therefore, Vysis' arguments based on the prosecution history are unconvincing. The Court reiterates and reaffirms its original claim construction that, in light of the specification and the prosecution history, the term "amplifying" only encompasses non-specific amplification.

4. Reconsideration Based on Newly Discovered Evidence

Finally, as its third and last ground for reconsideration, Vysis offers additional factual information that has become available through ongoing discovery since the June 20, 2001 Order. First, Vysis submits pages from the laboratory notebooks of Gen-Probe's Chief Scientific Officer. Second, Vysis provides snippets from the deposition of Dr. Mullis to show that Gen-Probe's expert allegedly construed the claim as encompassing PCR.

Assuming that Vysis' request were timely, newly discovered evidence normally provide proper grounds for reconsideration. School Dist. No. 1J, 5 F.3d at 1263. But, the grant of such motion lies within the discretion of the district court. Desert Gold Mining Co., 433 F.2d at 715. In this case, such new evidence might have supported Vysis' request for reconsideration.

The Court, however, declines to grant reconsideration on that basis because the consideration of such extrinsic evidence in claim construction is superfluous under the controlling patent law. "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed

claim term. In such circumstances, it is improper to rely on extrinsic evidence." Vitronics, 90 F.3d at 1583. Only when intrinsic evidence alone is insufficient may the Court use extrinsic evidence, and then only to aid the Court in "coming to the proper understanding of the claims" and the technology involved. Id. at 1584. Extrinsic evidence may not be used to vary or contradict the claim language. Markman, 52 F.3d at 981. In particular, "it is improper for a court to rely on extrinsic evidence such as expert testimony when construing disputed claim limitations." CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1318 (Fed. Cir. 2000) (citing Vitronics, 90 F.3d at 1584).

In this case, the Court cannot rely on either of Vysis' extrinsic evidence since they conflict with the intrinsic documents. Both the laboratory notebook pages and Dr. Mullis's deposition offered by Vysis are extrinsic evidence, since they are not part of the public record in the same way as are the patent specification and the prosecution history. Both documents directly contradicts the unambiguous meaning of the claim term as provided in the specification. Because those pages are extrinsic evidence that contradict the specification, the Court cannot consider them unless some ambiguity remains as to the meaning of the claims after a careful review of the intrinsic evidence. But, since the intrinsic evidence provides the requisite meaning to the disputed claim term, there is no need to turn to extrinsic evidence. Consequently, the Court declines to consider extrinsic evidence that was never part of the public record and that could not have given due notice to the public. Vitronics, 90 F.3d at 1583 ("One important consideration in claim construction is whether the patent has given adequate notice to the public of the proposed claim construction.").

In conclusion, the Court DENIES Vysis' request for reconsideration. That request was untimely under the local civil rules, inadequate under the law controlling reconsideration, and unsupported by the substantive patent law.

B. Gen-Probe's Motion for Partial Summary Judgment of Noninfringement under The Doctrine of Equivalents

"An element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." DeMarini Sports, 239 F.3d at 1331-32. To ascertain insubstantiality, courts have followed a tripartite test -- the "function-way-result" test -- to decide whether there is infringement under the doctrine of equivalents. See Warner-

Jenkinson, 520 U.S. at 40. Under that test, an accused device may infringe a claim under the doctrine of equivalents if it performs substantially the same overall function, in substantially the same way, to produce substantially the same overall result as the claimed invention. Unidynamics Corp., 157 F.3d at 1322. The analysis of insubstantiality under this "function-way-result" test "should be applied as an objective inquiry on an element-by-element basis." Warner-Jenkinson, 520 U.S. at 40.

The main issue at hand focuses on the amplification element in the patent claim: whether the differences between Gen-Probe's specific amplification step and the '338 patent's non-specific amplification step are insubstantial. In other words, the issue is whether the TMA amplification performs the same function, in the same way, and achieves the same result as the '338 patent. For the reasons provided below, the Court determines that there is an issue of fact for a jury to decide.

1. The Limitation by Limitation Analysis Must Occur in The Context of The Invention

"Infringement of process inventions is subject to the 'all-elements rule' whereby each of the claimed steps of a patented process must be performed in an infringing process, literally or by an equivalent of that step, with due attention to the role of each step in the context of the patented invention." Canton Bio-Medical, Inc. v. Integrated Liner Techs., Inc., 216 F.3d 1367, 1370 (Fed. Cir. 2001). See also Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532-33 (Fed. Cir. 1987).

Thus, for the Court to find infringement under the doctrine of equivalents, Vysis must prove that the differences between the invention's non-specific amplification and Gen-Probe's TMA specific amplification are insubstantial when viewed in the context of the invention. Warner-Jenkinson, 520 U.S. at 40 (noting that in a doctrine of equivalents determination, "an analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element"); IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1436 (Fed. Cir. 2000) ("In light of the similarity of the tests for equivalence under § 112, P 6 and the doctrine of equivalents, the context of the invention should be considered when performing a § 112, P 6 equivalence analysis just as it is in a doctrine of

equivalents determination."); Texas Instruments, Inc. v. ITC, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("It has long been recognized that the range of permissible equivalents depends upon the extent and nature of the invention . . . .").

Analyzing the insubstantiality of the differences in the context of the entire claim does not violate the "all-elements" rule as Gen-Probe argues. It is true that "the doctrine of equivalents must be applied to the individual elements of the claim, not to the invention as a whole." Warner-Jenkinson, 520 U.S. at 29. That rule prevents courts from applying the doctrine of equivalents to compare the whole invention with the whole accused product, and thereby completely vitiate one of the express limitations of the patent claim. See id. (explaining that this "all-elements" rule aims to "ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."). Cf. Gamma-Metrics Inc. v. Scantech Ltd., 52 U.S.P.Q.2d 1568, 1574 (S.D. Cal. 1998).

Yet, the "all-elements" rule does not preclude the Court from considering the interplay of all the limitations in the claim. Indeed, viewing the differences "in the context of the invention" is not an invitation to treat the individual patent limitations as insignificant or immaterial. Under this approach, Vysis must still prove the presence of every element or its equivalent in the accused technique. See Lemelson v. United States, 752 F.2d 1538, 1551 (Fed. Cir. 1985). And, the Court must still compare the patent claim and the accused technique elements by elements as required by precedent. Considering the context of the invention does not preclude the Court from performing its requisite element-by-element analysis. As the Supreme Court noted, "[c]onsideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform." Warner Jenkinson, 520 U.S. at 25. The Court may thus consider the context of the invention in its element-by-element analysis.

Moreover, to agree with Gen-Probe, the Court would have to blindly compare individual element by individual element in a contextual vacuum and risks granting summary judgment where material issues of fact may remain. In this case, Gen-Probe has supported its motion by submitting an expert declaration from Dr. Kary Mullis. Instead of comparing the disputed term in the context of the patent, the expert report only discusses the generalized differences between specific

amplification and non-specific amplification. To underscore its point, this generalized analysis relies upon the analogy of searching for a needle in a haystack. Specifically, it contends that specific amplification methods increase the copies of the needle until there are more copies of the needle than the haystack, while non-specific amplification amplifies both the needle and the haystack. (Declaration of Dr. Kary Mullis in Support of Gen-Probe's Motion for Partial Summary Judgment of Noninfringement under The Doctrine of Equivalents ("Mullis Decl."), at ¶¶ 22-23). Under such analysis, the differences appear to be substantial. Yet, Dr. Mullis' declaration does not address the situation in which the needle is amplified after it has been separated from the haystack. In that situation, the differences may not be as substantial as they first appear.

More importantly, if the Court were to blindly compare specific amplification with non-specific amplification as Gen-Probe would have it do, it would vitiate the first two limitations of claim 1 of the '338 patent. By relying on a straight comparison of specific versus non-specific amplification, the Court would ignore the target capture steps disclosed in the '338 patent and thereby vitiate those claim limitations through the application of the doctrine of equivalents. This action would be contrary to precedent. Consequently, the Court will determine whether the differences are insubstantial in an element by element approach while keeping in mind the entire context of the invention.

2. **There Are Issues of Material Facts Precluding Summary Judgment**

In this case, the parties do not discuss or dispute whether the accused product infringes, either literally or by equivalency, the target capture steps of the '338 patent. Thus, for the sole purpose of this motion, the Court will assume without deciding that Gen-Probe's HIV/HCV Assay uses a capture method equivalent to the one taught in the '338 patent.

The parties also agree that Gen-Probe's TMA amplification technique is an example of specific amplification. The parties do not dispute that "[t]he primers used in Gen-Probe's **specific** TMA amplification method have been carefully selected by Gen-Probe's scientists and are generally designed to bind to **specific**, unique sequences in a DNA or RNA molecule." (Vysis' Supplemental Statement of Disputed Facts, at ¶ 13) (emphasis added).

The dispute focuses on whether, within the context of the invention, the differences between the patent's non-specific amplification method and the accused technique are insubstantial. Gen-Probe

asserts that there are substantial differences requiring summary judgment, while Vysis raises issues of material facts to avoid summary adjudication.

The differences between specific and non-specific amplification appear significant at first. In specific amplification using two specific primers, the first specific primer will bind to the target sequence and provides the initiation site for primer extension into a new, complimentary strand of DNA. The second specific primer will then bind to the newly synthesized strand at the opposite end of the region to be amplified and enable the synthesis of the second DNA strand. Those two new strands will provide templates for additional copies. After enough cycles of copying, the specific target sequence would have been exponentially amplified millions to billions times. In contrast, non-specific amplification uses random hexamer primers, which are non-specific for the target sequence. Because of their short size, the random hexamers can and will bind to the target sequence as well as to other "background noise" sequences purely as a matter of statistical probability. After they bind to a random location on an unspecified nucleic acid, the random hexamer primers allow DNA polymerase to start DNA synthesis. The end result is the amplification of almost all nucleic acid found in the sample, be it the target sequence or the "background noise."

This situation is best illustrated using Dr. Mullis' haystack analogy. Both technologies focus on finding and multiplying the proverbial "needle in the haystack." In the specific amplification method, a specific and magnetic "probe" would find the needle and bind to it, but not to the hay. Then, multiplication would occur based on the probe and the end result is a billion needles compared to some leftover hay. In contrast, in non-specific amplification, the "probe" will find and bind to any long and fine items, including needle and hay. After sufficient cycles of non-specific multiplication, there would be a billion needles along with a billion copies of each straw, resulting in a needle stack but also a large number of haystacks.

This case is, however, not as simple as that example suggests because the application of target capture, as required by both the patented invention and Gen-Probe's technique, theoretically isolates the target nucleic acid before amplification. Specific or non-specific amplification after target capture may function in the same way and achieve the same result.

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An illustration would underscore this point. To expand on the "needle in the haystack" example, the first step in the invention and the accused technique is to "target capture" the needle. The target capture method would theoretically isolate and remove the needle from the haystack. The needle then becomes its own stack. In this new stack, the specific "probe" would still find the isolated needle and amplify it. The non-specific "probe" would still bind to any long and fine items in the stack. But, since there is only the needle in the stack, the amplification would result in a large number of needles.[4]

As that example shows, a reasonable jury may differ about the insubstantiality of the differences after hearing from the parties' experts. A jury may find that, after target capture, specific and non-specific amplifications do not perform the same function (Mullis Decl., at ¶¶ 18-25), in the same way (Id., at ¶¶ 26-36), or achieve the same result (Id., at ¶¶ 37-42). But then, a reasonable jury could also find that both techniques provide the same function (Persing Decl., at ¶¶ 6-7), act in the same way (Id., at ¶¶ 8-9, 12-13), and reach the same result (Id., at ¶¶ 14-16). Likewise, a jury could determine that the two techniques do not act in the same way. (Mullis Decl., at 122; Persing Decl., at ¶¶ 8-15). Where a reasonable jury may differ, there are triable issues of fact.

As the Federal Circuit has recognized, district courts have great discretion in denying summary judgment. Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1364 (Fed. Cir. 2001) ("In reviewing a denial of a motion for summary judgment, we give deference to the trial court, and 'will not disturb the trial court's denial of summary judgment unless we find that the court has indeed abused its discretion.'") (quoting Suntiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1333 (Fed. Cir. 1999)); Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1306 (Fed. Cir. 2000). In this exercise of its discretion, the Court has determined that triable issues of fact exist, precluding the grant of summary judgment of noninfringement under the doctrine of equivalents.

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[4] As the patent acknowledges, target capture is not perfect in practice, and "background noise" may remain. But, since neither party raised that issue either in their briefs or declarations, the Court will not belabor that point further.

IV. CONCLUSION

For the reasons provided above, the Court DENIES Vysis' request for reconsideration of the June 20, 2001 Order and DENIES Gen-Probe's motion for partial summary judgment of noninfringement under the doctrine of equivalents.

IT IS SO ORDERED.

Dated: 11/19/01

MARILYN L. HUFF, Chief Judge
UNITED STATES DISTRICT COURT

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